

### **REMARKS/ARGUMENTS**

By the foregoing amendment, claims 19, 22, 24-25, 28, 37-40, 43-48 and 51 have been amended to clarify the subject matter being claimed and to eliminate unnecessary limitations. Also, claims 36, 49 and 50 have been cancelled due to redundancy. No new matter has been added. Support for the amendments is found throughout the specification, including but not limited to Figures 6A-6E and the written description associated with those figures. Reconsideration is requested.

#### **Claim Objections**

In the office action, claims 24-25, 28, 36, 38-40 and 43-51 were objected to on various technical grounds. By the foregoing amendment, changes have been made to the language of claims 24-25, 28, 38-40, 43-48 and 51. Also, claims 36, 49 and 50 have been cancelled. It is believed that these changes have overcome the stated objections.

#### **Obviousness-Type Double Patenting Rejection**

In the Office Action, claims 1-18 were rejected only on grounds of obviousness-type double patenting over claims 1-18 of US Patent No. 6,726,677. Filed herewith is a Terminal Disclaimer which overcomes this obviousness-type double patenting rejection.

#### **35 U.S.C. §101 Rejections**

In the Office Action, claims 21 and 51 were rejected under 35 U.S.C. §101 on grounds that aspects of the anatomical vessel were recited as affirmative elements of the invention. Applicant respectfully disagrees with these stated grounds for rejection. It is permissible for method claims to recite anatomical structures or aspects of anatomical structures in connection with positioning or use of a device. Without implying any agreement with the stated grounds for rejection, Applicant has amended claims 21 and 51 to clarify the method step limitations recited therein. Claims 21 and 51, as now amended, are believed to fully comply with the requirements of 35 U.S.C. §101.

#### **35 U.S.C. §102 Rejection**

In the Office Action, independent claim 19 was rejected only under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 4,950,267 (Ishihara, et al.). Ishihara et al. describes a laser beam irradiation apparatus that comprises a laser generating device, a laser beam irradiation probe for applying a laser beam from the laser generating device to a region of an object of irradiation, an ultrasonic transmitter/receiver for emitting ultrasonic waves toward the region to which the laser beam is applied by the probe, receiving reflected waves from the irradiated region, and converting the reflected waves into an electrical signal, a measuring device

for measuring the temperature of the irradiated region in accordance with the electrical signal from the ultrasonic transmitter/receiver, and an output adjuster for adjusting the output of the laser generating device in accordance with a temperature signal from the measuring device.

As amended, Applicant's independent claim 19 recites a method A method for delivering a guidewire or other apparatus from a catheter positioned within a vessel within a patient's body to a target location outside of that vessel, such method comprising the steps of: (A) positioning, within the vessel, a catheter device that comprises a catheter body, a tissue penetrator that has a lumen and is passable from a location on the catheter body, at least one catheter orientation apparatus useable to orient the catheter such that the tissue penetrator will penetrate from the catheter to a desired target location and a stabilizer for stabilizing at least a portion of the catheter body within the vessel; (B) using the catheter orientation apparatus to orient the catheter such that the tissue penetrator will enter the target locations when the tissue penetrator is subsequently passed from the catheter body; (C) stabilizing the catheter body within the vessel; (D) passing the tissue penetrator from the stabilized catheter body through the wall of the vessel and to the target location; and delivering a guidewire or other apparatus through the penetrator lumen to the target location. The subject matter of this claim is patentably distinguishable over Ishihara et al. for a number of reasons.

The Office Action specifically cites Figure 2 of Ishihara et al., which is reproduced below:

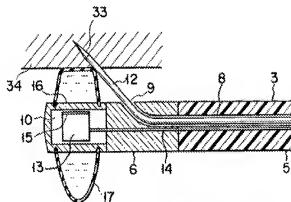


FIG. 2

Item 33 which advances from the instrument channel of an endoscope is a "laser probe." It is devoid of any lumen through which a guidewire or other device could be delivered. Ishihara et al. describes the function of this device, in part, at column 4, lines 8-18, as follows:

When the position of the tumorous region is detected by the ultrasonic scanning, laser probe 12 is introduced into the body cavity through instrument channel 8 of endoscope 1, and distal tip 33 of the probe is thrust into the affected part. A laser beam is emitted from laser generating unit 26, and is transmitted through laser probe 12. Thus, the tumorous region is irradiated with the laser beam from tip 33. The affected part is warmed to a temperature of 42.degree. to 43.degree. C. by means of the laser beam, and this temperature is maintained for, e.g., 20 to 30 minutes for thermotherapy.

To modify Ishihara's laser probe such that it would include a hollow lumen would be contrary to Ishihara's objective of delivering laser light to the tumor tissue. This is so because hollowing out the laser probe would necessarily decrease the functional cross-sectional area of the laser-carrying optical fibers capable of being housed in the probe, thereby decreasing the amount of laser light that can pass through the probe. Thus, Ishihara et al. fails to teach or render obvious a tissue penetrator having a lumen and the step of delivering a guidewire or other apparatus through the penetrator lumen to the target location" as recited in amended independent claim 19.

Accordingly, as amended, independent claim 19 is patentably distinguishable over Ishihara et al.

**CONCLUSION**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

/William L. Haynes, Reg. No. 48,151/  
William L. Haynes  
Registration No. 48,151  
Attorney for Applicant

Medtronic Vascular, Inc.  
3576 Unocal Place  
Santa Rosa, CA 95403  
Facsimile No.: (707) 543-5420